

Application No. 09/977,154
Amendment "I" dated May 20, 2005
Reply to Office Action mailed April 7, 2005

REMARKS

Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 1-18, 20-21 and 23-33 are pending, wherein claims 1 and 17 have been amended. Claim 1 was restored to how it read before the immediately preceding amendment and therefore raises no new issues that have not already been considered in an action on the merits. Claim 17 was amended to restore language deleted by the immediately preceding amendment. In this way, every new matter rejection ever raised by the Examiner can be dealt with in a single amendment and/or on appeal in the event the PTO maintains the final rejection. As discussed below, both the CCPA and Federal Circuit have explicitly held that drawings can be relied on to provide written description support for proportional comparisons added to claims during prosecution but not explicitly described in the specification.

1. NEW MATTER OBJECTION

The Office Action objects to the specification under 35 U.S.C. § 132 on the grounds that the previous amendment introduced new matter into the specification, more particularly to the following phrase added previously to independent claims 1, 17, 21, 24, and 29: "the interference screw having an overall length in order for the interference screw to apply force along a greater distance in the cancellous bone region compared to the cortical bone region". This is the same type of objection stated in the previous Office Action relative to the following phrase added previously to claims 1, 17, 21, 24 and 29, and which is included in claims 1 and 17 as now amended: "the distal threaded section having a length that is greater than the length of the proximal threaded section in order for the interference screw to apply force along a greater distance in the cancellous bone region compared to the cortical bone region". The arguments set forth herein address both objections. Since both limitations have been considered on the merits, both are appropriately included in this amendment for final resolution, possibly by appeal if necessary.

Both objections are without merit because they ignore the plain teachings in both the specification and drawings that imply, if not explicitly teach, one or more embodiments of an interference screw in which (1) the distal threaded section is longer than the proximal threaded section and (2) in which the interference screw has an overall length in order for the distal

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threaded section to apply force along a greater distance in the cancellous bone region of a bone tunnel than the cortical bone region during use.

In paragraph [050] of the specification, a preferred interference screw is described that has a length "within the range of approximately 35 mm to approximately 40 mm". An interference screw having a length in this range is also described in originally filed claim 16, which also forms part of the originally-filed specification. Claim 23, which depends from claim 16, further defines an interference screw "wherein the proximal threaded section has a length of about 5 mm". This claim was first introduced in Amendment "A" dated September 29, 2003 without objection and is supported by the teaching found in paragraph [050] that "according to one preferred embodiment, the length of proximal end 22 is specifically configured to accommodate the thickness of the cortical bone region of the tibia, which is approximately 5 mm thick". Claim 23, which was accepted without objection when introduced and depends from claim 16, defines an embodiment of an interference screw that is approximately 35-40 mm long and which has a proximal threaded section that is about 5 mm long. Claim 23 therefore defines an embodiment in which the distal threaded section is longer than the proximal threaded section by simple mathematical deduction, which can be performed by one of ordinary, or even minimal, skill in the art. Claims 16 and 23, as well as paragraph [050], provide clear written description support showing that Applicant had possession of the invention claimed in claims 1 and 17 as previously amended and also as now amended.

Moreover, Figures 6 and 7 clearly depict embodiments in which the distal threaded sections 62, 72 are longer than the respective proximal threaded sections 64, 74. More particularly, distal threaded section 62 of Figure 6 is clearly longer than proximal threaded section 64, as shown by the brackets. Similarly, the distal section 72 of Figure 7 is clearly longer than proximal section 74, as shown by the brackets. As for the embodiment shown in Figure 4, the proximal threaded section has an angled face. While one side of the proximal threaded section 22 may appear to be about the same length as the distal threaded section 24, as shown by the brackets in Figure 2, the shorter side of proximal threaded section 22 is clearly shorter, as clearly shown by the brackets in Figure 4. This distinction was discussed in the previously-filed amendment. Moreover, Figure 4 clearly shows that the interference screw 10 has an overall length such that it extends, and therefore applies force, along a greater distance in the cancellous bone region 36 compared to the cortical bone region 34 of the bone tunnel 30. Thus, Figures 4,

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6, and 7 also show unambiguous support for the "new matter" alleged in both the present and previous office actions.

As held by the CCPA in *In re Heinle*, "it is proper in support of claims which otherwise could not be allowed, to amend the specification of a pending application to include new matter clearly and conclusively disclosed by the drawings." 145 USPQ 131, 136 (CCPA 1965) (quoting *Bloodhart v. Levernier*, 20 CCPA 917, 64 F.2d 367, 17 USPQ 188). The court further reversed the Examiner and Board, which had rejected as constituting new matter a claim amendment that introduced a proportional relationship between two structural elements shown in the drawings but not mentioned "in the words of the specification". *In re Heinle*, 145 USPQ at 136 (emphasis in original). The proportional relationship in question (*i.e.*, "approximately one-fourth of the circumference") was not described in the specification but was shown in the drawings. The CCPA reasoned that since it would have been proper to amend the specification based on the drawings to include the proportional relationship, it follows that adding the proportional relationship to the claims was also proper: "Since we believe an amendment to the specification to state that one-fourth of the circumference is the aperture width would not violate the rule against 'new matter,' we feel that supporting disclosure exists. This rejection was therefore in error." *Id.* This holding supports Applicant's claim amendments in the two previously-filed amendments, both of which are carried forward in this amendment.

The decision by the CCPA in *In re Wolfensperger*, 133 USPQ 537 (CCPA 1962) yielded a similar outcome. Even though the size proportions added by amendment were not described anywhere in the specification, the court overruled the rejection of the claims because the proportions were shown in the drawings. 133 USPQ at 543-45. More importantly to the present objection, the court rejected the argument offered by the PTO Solicitor that "patent application drawings are not presumed to be drawn to scale or correct proportion." 133 USPQ at 545 (emphasis added). "We find nothing [in the case law cited by the Board] which raises a presumption that drawings such as those here are not drawn to scale with reasonable accuracy." *Id.* "We think the showing of the drawings can be relied on to the extent they have been by applicant." *Id.* In other words, it was reversible error for the PTO to presume that drawings are not drawn to scale absent a teaching that they are not (*e.g.*, that they are merely "schematic").

In short, absent teachings or evidence to the contrary, an Applicant may rely on proportions shown in the drawings when amending claims. Because it is reversible error for the

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PTO to reject claims on the grounds that "patent application drawings are not presumed to be drawn to scale or correct proportion," as was held in *In re Wolfensperger*, it follows that the new matter rejections in this and the previous Office Action likewise constitute reversible error since they are premised on the similar allegation that "there is no statement in the specification that the drawings are to scale". Office Action, page 4 (emphasis added).¹ According to the CCPA, no such statement is necessary as no such statement was contained in the applications in either *In re Heinle* or *In re Wolfensperger*. Moreover, the same type of argument made in the current Office Action was clearly and unambiguously rejected by the CCPA in *In re Wolfensperger*. 133 USPQ at 545.

Moreover, both *In re Wolfensperger* and *In re Heinle* remain good law since they were cited approvingly and affirmed by the Federal Circuit in *Vas-Cath Inc. v. Mahurkur*, 935 F.2d 1555, 1564-65 (Fed. Cir. 1991). Finally, *Vas-Cath Inc. v. Mahurkur* is cited in section 2163.02 of the MPEP, which states that drawings alone can, in fact, support new claim amendments added subsequent to filing of the application. In view of the clear authority of the CCPA, Federal Circuit and MPEP, Applicant submits that the alleged new matter objections set forth in this and the previous Office Actions are clearly erroneous and constitute reversible error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the new matter objection to the specification.

Finally, the Office Action states that the added limitation "contradicts Applicant's disclosure (page 6, para [015], lines 4-7) where Applicant states that the compressive forces applied in the cortical bone regions are greater than the compressive forces applied within the cancellous bone regions because the diameter of the proximal cylindrical section is greater than the diameter of the distal cylindrical section." In response, Applicant maintains that there is no contradiction. The two concepts actually complement, rather than contradict, each other. As discussed throughout the application, including the section cited in the Office Action, the distal threaded section has a smaller diameter than that proximal threaded section in order for the interference screw to exert a lower compressive force against a soft tissue graft in the cancellous bone region than in the cortical bone region. That relationship remains true regardless of the

¹ It should be pointed out that Figure 4, for example, "illustrates a cross-sectional view of the interference screw of Figure 1, inserted within a tunnel in a bone. . . ." There is no basis for assuming that this drawing is drawn so wildly out of proportion as to grossly misrepresent the relative thicknesses of the cancellous and cortical regions 36, 34, and the length of screw 10.

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relative lengths of the proximal and distal threaded sections. To say that the interference screw applies "force along a greater distance in the cancellous bone region compared to the cortical bone region" in no way means or implies that the distal threaded section exerts greater compressive force in the cancellous bone region compared to the compressive force exerted by the proximal threaded section in the cortical bone region. It is simply illogical for the PTO to argue that "greater distance" means "greater compressive force".

By way of analogy, consider a 4 inch long screw having a thread diameter of 2 mm and a 2 inch long screw having a thread diameter of 4 mm. If both were inserted into 4 inch long holes located side-by-side having initial diameters of 1.9 mm, the 4 inch long screw will clearly exert force against its respective hole along a greater distance (i.e., 4 inches versus 2 inches). Yet the 2 inch long screw will exert greater compressive force against the hole wall by virtue of its greater thread diameter (i.e., 4 mm versus 2 mm). Thus, there is no contradiction between the claims as amended and the teachings of the specification because there is no contradiction between a longer but narrower distal threaded section exerting force along a greater distance than a shorter but thicker proximal threaded section, even though the proximal threaded section exerts greater compressive force by virtue of its greater diameter.

II. WRITTEN DESCRIPTION REJECTION

The Office Action rejects claims 1-18, 20-21 and 23-33 under 35 U.S.C. § 112, first paragraph, on the grounds that the claims allegedly "contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Note comments made under 'Response to Amendment.'" Office Action, page 2. Under the heading "Response to Amendment", the Office Action provides, as the sole basis for this rejection, the following statement: "Although Applicant states that the drawings are to scale, there is no statement in the specification that the drawings are to scale." The Office Action cites to no section of the MPEP or case law in support of its contention that drawings must be presumed to be drawn out of scale absent a statement in the specification that they are, in fact, drawn to scale.

During informal telephonic interviews, the Examiner has repeatedly stated that Applicant may not rely on the apparent proportions and comparative relationships depicted in the drawings.

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When asked to provide a basis for this position, the Examiner at first referred to MPEP § 2125, which by its very terms applies only to a prior art rejection, not rejections based on whether an applicant has complied with the written description requirement of 35 U.S.C. § 112, first paragraph.

MPEP § 2163.02, which is the proper section governing issues relating to written description, explicitly states that "[a]n applicant shows possession of a claimed invention . . . using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention" (emphasis added). This section also cites *Vas-Cath Inc. v. Mahurkur*, discussed above, which held that drawings alone can form the basis of a claim, particularly since design patents contain only drawings but no written description and yet cannot be said to lack written description showing possession of the invention depicted. 935 F.2d at 1564. *Vas-Cath* further analogized drawings in design patents to drawings in electrical and chemical cases, which are often the only support found in an application for claims to circuitry or chemical structures. *Id.* Since drawings in design patents, electronic patents, and chemical patents all provide written description support in the absence of words, the court reasoned that, in general, drawings alone can satisfy the written description requirement of 35 U.S.C., § 112, first paragraph, citing *In re Wolfensperger* and *In re Heinle* in support of this holding. *Vas-Cath Inc. v. Mahurkur*, 935 F.2d at 1564-65.

As discussed above, the CCPA, in both *In re Wolfensperger* and *In re Heinle*, found there to be explicit written description support for specific proportional (i.e., numeric) relationships added after filing by claim amendment even though no such numeric relationships were described anywhere in the specification. The drawings alone provided the specific proportions added to the claims. Indeed, the CCPA in *In re Wolfensperger* explicitly rejected as reversible error the argument by the PTO that "patent application drawings are not presumed to be drawn to scale or correct proportion," 133 USPQ at 545 (emphasis added). The court went on to state that "[w]e find nothing [in the case law cited by the Board] which raises a presumption that drawings such as those here are not drawn to scale with reasonable accuracy." *Id.* Based on this, the court concluded that "[w]e think the showing of the drawings can be relied on to the extent they have been by applicant." *Id.* Hence, an applicant may rely on proportions shown in the drawings.

In *In re Heinle*, the CCPA reversed the Examiner and Board, which had rejected as constituting new matter a claim amendment that introduced a proportional relationship between

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two structural elements shown in the drawings but not mentioned "in the words of the specification". *Heinle*, 145 USPQ at 136. The proportional relationship in question (*i.e.*, "approximately one-fourth of the circumference") was not described in the specification but was reasonably shown in the drawings. The CCPA reasoned that since it would have been proper to amend the specification based on the drawings to include the proportional relationship, it follows that adding the proportional relationship to the claims was also proper: "Since we believe an amendment to the specification to state that one-fourth of the circumference is the aperture width would not violate the rule against 'new matter,' we feel that supporting disclosure exists. This rejection was therefore in error." *Id.* (emphasis added).

The Federal Circuit in *Vas-Cath Inc. v. Mahurkur* cited the holdings of both *In re Wolfensperger* and *In re Heinle* when determining whether drawings alone (*i.e.* of a parent design application) can provide written description support sufficient to show that an applicant was "in possession" of the later-claimed invention at the time the parent design application was filed. Because *Vas-Cath Inc. v. Mahurkur* is cited multiple times in MPEP § 2163.02 when defining the rules for written description support, the MPEP also incorporates *In re Wolfensperger* and *In re Heinle*, since both were quoted liberally and approvingly in *Vas-Cath v. Mahurkur*.

Applying the facts and holdings of *In re Wolfensperger* and *In re Heinle* to the present case, it is clear that the Office Action fails to state any legally cognizable rational for rejecting the claims under 35 U.S.C. § 112, first paragraph, *i.e.*, that the Applicant was not "in possession of the claimed invention" recited in the claims as now amended. Proportional relationships found only in the drawings were held to provide explicit written description support for later-added claim amendments in each of *In re Wolfensperger*, *In re Heinle*, and *Vas-Cath Inc. v. Mahurkur*. Because the drawings in the present application provide clear support for the claim language in question, the application as filed clearly provides written description support showing that applicant "had possession of the claimed invention" based on the drawings alone.

Moreover, the specification as originally filed also provides actual written support. The specification teaches that the cortical bone region can be 5 mm thick. ¶ [050]. The specification also teaches that interference screws can have a length of about 35 mm to about 40 mm. ¶ [050]. That means that such interference screws, when inserted into a bone tunnel, will exert force along a greater length in the cancellous bone region compared to the cortical bone region (*e.g.*, as

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clearly shown in Figure 4). It also means that the distal threaded section in such interference screws is longer than the proximal threaded section. Subtracting 5 mm, representing an embodiment of the length of the proximal threaded section, from 35-40 mm leaves 30-35 mm remaining in the screw, most or all of which comprises the distal threaded section. For this additional reason, Applicant submits that the specification as originally filed provides written description support for the claims as now presented.

III. ART REJECTION

The Office Action rejects claim 34 under 35 U.S.C. § 103 as obvious over U.S. Patent No. 2,382,019 to Miller in view of U.S. Patent No. 6,387,129 to Rieser et al. What is interesting about this rejection is that the interference screw of Rieser et al. is clearly closer in design and function to the inventive interference screw defined in claim 34. The screw in Miller is not designed for use as an interference screw to secure a soft tissue graft or for any medical use whatever. It is designed to be hammered into wood, followed by screwing it the rest of the way into the wood. Col. 1, line 50 – col. line 2; col. 2, lines 44-51; col. 3, lines 5-12. To achieve this desired function, the Miller screw includes a head and is made from metal so as to be capable of receiving strong blows from a hammer. It also includes an elongate unthreaded, nail-like tip that is designed to behave as a nail when receiving hammer blows. See Figures 1-4. These or similar features are necessary in order for Miller to be capable of performing its intended function, i.e., of being initially hammered into wood, followed by screwing it in the rest of the way. In addition, the Miller screw includes a thread 3, 3', 3", or 3''' that terminates shy of the head 1, 1', 1", or 1''' such that the screw includes a threadless cylindrical portion between the upper limit of the thread 3, 3', 3", or 3''' and head 1, 1', 1", or 1'''. See Figures 1-4.

The Office Action fails to state a *prima facie* case of obviousness relative to claim 34 because it fails to show where the combined references teach or suggest every limitation found in the claim. The interference screw of claim 34 includes "a threaded body extending between a proximal end and a distal end". The threaded body further includes a "proximal threaded section", "a distal threaded section", and "a single continuous thread", with "the proximal threaded section terminating at said proximal end" and "the proximal end terminating said proximal threaded section having an angle relative to the central axis" (emphasis added). Thus,

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the interference screw of claim 34 is threaded all the way to the angled end of the proximal end of the interference screw.

Not only does Miller, the primary reference, fail to teach or suggest a screw that is threaded all the way to an angled proximal end, the Office Action fails to even address this limitation. Since Miller, not Rieser et al., is the primary reference, the features of Rieser et al. are entirely irrelevant unless and until the PTO establishes that one of skill in the art would have been motivated to modify the Miller screw to include one or more of the features disclosed in Rieser et al. The PTO has made no showing or argument of any kind with respect to a screw being threaded all the way to an angled proximal end. Because MPEP § 2142 requires the PTO to show where the prior art teaches or suggests every claim limitation to establish *prima facie* obviousness, the Office Action fails to state a *prima facie* case of obviousness relative to claim 34.

Moreover, it appears that the Office Action strategically cited Miller as the primary reference rather than Rieser et al. to avoid having to address the comparative study submitted and discussed in previous amendments. The comparative study clearly shows that *one single* interference screw within the scope of claim 34 was surprisingly and unexpectedly more effective in retaining a soft tissue graft within a bone tunnel compared to *two* bicortical fixation screws within the scope of Rieser et al. Based on that study, there is no way the PTO could sustain an obviousness rejection using Rieser et al. as the primary reference absent contrary evidence. The tactic of using Rieser et al. as the secondary reference likewise fails for various reasons, not the least of which is the fact that Miller, as primary reference, fails to teach or suggest a screw that is threaded all the way to an angled proximal end, as discussed above.

Moreover, because Miller is the primary reference, the proper inquiry is whether the proposed modification would yield a screw that is still satisfactory for the intended purpose of *Miller*, not Rieser et al. If the proposed modification is such that the Miller screw is no longer satisfactory for its intended purpose, or changes its principle of operation, such modification is nonobvious as a matter of law according to MPEP § 2143.01.

As discussed throughout Miller, the intended function or principle of operation of the Miller screw is that it can be hammered into wood initially and then screwed in the rest of the way in. Col. 1, line 50 – col. line 2; col. 2, lines 44-51; col. 3, lines 5-12. Modifying the Miller screw so as to remove the head and the unthreaded cylindrical section to yield a modified device

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having an angled proximal end would alter the principle of operation of the Miller screw because it would interfere with or prevent its ability to be hammered into wood. Wood is a relatively hard material. It is well known to those of skill in the art that forces from a hammer are most effectively transferred to the shaft of a nail or screw when the proximal head or surface of the nail or screw is perpendicular to the shaft. Providing a head or proximal end that is perpendicular to the shaft helps ensure that forces are transferred axially from the hammer to the shaft of the screw or nail. When the force from the hammer blow is transverse rather than axial (*i.e.*, where the hammer fails to strike the nail head on), the nail or screw tends to either fly out to the side or bend. That is why nails and screws intended to be hammered have surfaces or heads that are perpendicular to the shaft. Modifying the proximal end to have an angled surface (*i.e.*, between about 10-80° relative to the central axis of the screw) would make it far more difficult to hammer a nail or screw into wood because it would interfere with the ability to axially transfer forces from the hammer to the shaft of the nail or screw.

The angled proximal end would act as a camming surface that transfers a significant amount of force from the hammer into a direction transverse to the axis of the screw shaft. The effect of this would be a tendency of the proximal end of the screw to deflect sideways rather than being driven straight down into the wood. It is well-known to anyone who has ever tried to hammer a nail or screw into wood that the hardest part is the initial penetration. Failure to hit the nail or screw head on initially can cause the nail or screw to fly off the wood surface and/or become bent. However difficult this process may be when using properly designed nails and screws that have perpendicular heads or proximal ends, altering the proximal end or head so as to have an angle between about 10-80° relative to the central axis of the screw would only exacerbate the problem. It would make it virtually impossible to transfer sufficient axial force from the hammer to the screw shaft to offset the tremendous destabilization effect of the transverse force caused by the angled end or head. In view of this, Applicant submits that one of skill in the art would not have been motivated to modify the Miller screw to have an angled proximal end with an angle between about 10-80° relative to the central axis of the screw. Such a modification would greatly reduce the ability of such a screw to be hammered into wood. In other words, such a modification would render the Miller screw unsatisfactory for its intended purpose and/or change its principle of operation, in violation of the clear strictures set forth in MPEP § 2143.01.

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Moreover, the alleged motivation for combining Miller and Rieser et al. set forth in the Office Action is illogical because it rests on the unstated (and unsupported) assumption that it would be desirable to insert the Miller screw at an angle relative to the wood surface. It also ignores the fact that the Miller screw is specifically designed to be initially hammered into wood and then screwed the rest of the way in. The Office Action alleges that "it would have been obvious to one of ordinary skill in the art . . . to have provided the Miller screw with an angled proximal end, as taught in Rieser et al., so that the Miller screw would be flush with the outer surface of material [in] which it is placed." This reasoning is unpersuasive for several reasons.

First, screws and nails are ordinarily driven in at an angle that is perpendicular to the wood surface. As discussed above, nails and hammerable screws include heads or proximal ends that are perpendicular to the nail or screw shaft to facilitate the axial transfer of force from the hammer to the shaft. Nail and screw heads that are perpendicular to the shaft inherently lie flush to the wood surface whenever the nail or screw is successfully inserted at an angle that is perpendicular to the wood surface since they lie in the same plane. Thus, providing a head that is perpendicular to the screw shaft would be the best way to ensure the head lies flush to the wood surface, thus leading away from the modification proposed by the Examiner (*i.e.*, providing a head with an angle of about 10-80° relative to the shaft).

Second, even assuming the desirability of hammering the Miller screw into wood at an angle, followed by screwing it the rest of the way in so as to lie flush to the wood surface, providing an angled proximal end would not facilitate this result. As discussed above, it is often difficult to accurately transfer forces from a hammer blow axially through the shaft of a nail or screw of normal design. Modifying the Miller screw to have an angled head or proximal end would greatly exacerbate this difficulty, even when the screw is driven perpendicularly into the wood, as discussed above. However, attempting to hammer the Miller screw into wood at an angle that equals the angle of the angled proximal end would be virtually impossible. For example, if the Miller screw were modified to have an end that is offset from perpendicular by 20°, it would be necessary for the screw to be initially hammered into the wood at an angle that is also offset from perpendicular by exactly 20°. Otherwise, the angled end would not lie flush with the wood surface. Given the difficulties of hammering a screw having an angled end, Applicant submits that it would be virtually impossible for a user to ensure that the screw is initially hammered into wood at an angle that exactly corresponds to the angle of the proximal end. In

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view of this, one of skill in the art would clearly not have been motivated to modify the Miller screw for the reason set forth in the Office Action (*i.e.*, in an attempt to achieve a demonstrably unachievable result).

Moreover, there is no reasonable expectation of success that a screw having an angled face could be hammered into wood at an angle that exactly corresponds to the angle of the proximal end in order for the proximal end to lie flush with the wood surface, as urged by the Examiner. More importantly, the Examiner has not provided any evidence in the prior art showing any reasonable expectation of success of angling the proximal end of a hammerable screw and then actually hammering it into wood at that same angle.

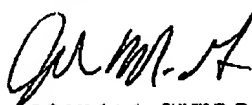
IV. CONCLUSIONS

In view of the foregoing, Applicant submits that the application is in allowable form. At the very least, the amendment is proper for entry because it places the application in better condition for appeal of the alleged "new matter" rejections by combining all of such rejections already considered on the merits.

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 20th day of May 2005.

Respectfully submitted,



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